Remarks

Lack of unity has been found among claim groups I – IX. Applicants elect the claims of Group I, constituting claims 1-30 and 35-44. In response to the Examiner's peptide election requirement, applicants elect the peptide SEQ ID NO: 5. The elections are made with traverse.

General Finding of Lack of Unity Among Groups I - IX

Examiner's contention that there are nine (9) different inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT rule 13.1 is incorrect. Specifically, PCT Rule 13.2 states:

> Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

MPEP, Rev. 3, August 2005, Appendix T, pg. T-48.

The "special technical features" that define the contribution that each of the claimed inventions in Groups I – IX make over the prior art are the novel heparin binding peptides of claims 1 and 35.

The peptides are recited in every claim, as either a peptide *per se* (Group I), or conjugates thereof with an active agent (Group IV) or carrier molecule (Group VIII). The peptides and conjugates are related as intermediate and final product. The peptides and conjugates thus meet the following test for unity:

(A) The intermediate and final products have the same essential structural element, in that:

(1) The basic chemical structures of the intermediate and the final products are the same, or

(2) The chemical structures of the two products are technically closely interrelated, the intermediate incorporating an essential structural element into the final product; and

(B) The intermediate and final products are technically interrelated, this meaning that the final product is manufactured directly from the intermediate or is separated from it by a small number of intermediates all containing the same essential structural element.

MPEP 1850, III. C, Rev. 3, Aug 2005, pg. 1800-99

Manifestly, the chemical structures of the peptides and the conjugate are technically closely related, since the peptides are incorporated into the conjugates. This relationship satisfies condition (A), above. The peptides and conjugates are closely related, as the conjugates are either made directly from the peptides or are separated by a small number of intermediates containing the same essential structural element, i.e., the peptides. This relationship satisfies condition (B) of the intermediate/product unity test. Thus, unity of invention exists between the peptides of Group I, as intermediate, and the conjugates of Groups IV and VIII, as products.

Unity of invention also exists between the peptides (Group I), conjugates (Groups IV and VIII), and the methods of Groups II, III, V, VI, VII and IX, pursuant to MPEP 1850 1850, III, A:

> The method for determining unity of invention under PCT Rule 13 shall be construed as permitting, in particular, the inclusion of any one of the following combinations of claims of different ***categories*** in the same international application:
>
> (A) In addition to an independent claim for a given product, an independent claim for a process specially adapted for the

> manufacture of the said product, and ***an independent claim for a use of the said product.***

MPEP 1850, III, A., Rev. 3, August 2005, pg. 1800-97, emphasis added.

Groups II, III, V-VII and IX contain claims to treatment methods using the claimed peptides or conjugate. These treatment methods are "uses" within the meaning of the above test for unity between product and use. Thus, the method claims of Groups II, III, V-VII and IX share unity with the peptide and peptide conjugate claims of Groups I, IV and VIII. All claim groups therefore share unity pursuant to PCT Rule 13.1.

Unity is also present among all claim groups because the claims of Groups II – IX are dependent on either claim 1 or claim 35 of Group I. Each of the claims of Groups II - IX incorporate all of the limitations of the peptides defined in claims 1 or 35. As all claims of Groups II – IX depend directly or indirectly from claim 1 or 35, the claims of Groups II-IX cannot constitute separate inventions from their base claims. This position is supported by the MPEP which states:

> Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims. By "dependent" claim is meant a claim which contains all the features of one or more other claims and contains a reference, preferably at the beginning, to the other claim or claims and then states the additional features claimed (PCT Rule 6.4).... If the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims. In particular, it does not matter if a dependent claim itself contains a further invention.

MPEP, 1850, II, Rev. 3, August 2005, pg. 1800-96.

Therefore, unity of invention exists as among the claims of Groups I - IX. Applicants respectfully request reconsideration and removal of the lack of unity finding.

Peptide Markush Group – Lack of Unity

Examiner further alleges that "[t]he inventions (Products or Methods) are independently drawn to a Markush group of distinct peptides." It is not clear which Markush group does not meet PCT unity of invention requirements or to which Markush group examiner's comments even apply. Examiner identifies SEQ ID NO: 2 and SEQ ID NO: 3 as examples. While SEQ ID NO: 2 and SEQ ID NO: 3 belong to the Markush group of claim 13, they are not themselves separate heparin binding peptides. Rather, SEQ ID NO: 2 and SEQ ID NO: 3 are sequence units from which R_1, R_2, and R_3 may be chosen in preferred embodiments of the formulas of the novel heparin binding peptides of claim 1. More importantly, claim 13 directly depends from claim 1. In view of the presence of a generic claim ***embracing*** the peptides containing the sequence units SEQ ID NO: 2 and SEQ ID NO: 3, the presence of those alternative sequence units in claim 13 does not deprive any claims of unity. As noted above, if "the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims." MPEP 1850, II., Rev. 3, August 2005, pg. 1800-96.

It is further pointed out that Examiner has already indicated that claims in Group I possess a "unique special technical feature" sufficient to make them acceptable as a singular invention for PCT unity of invention purposes. Examiner's assertion that the Markush group of claim 13 now lacks unity of invention is inconsistent with this earlier conclusion, and is improper under MPEP 1850, II.

In addition to incorrectly examining the Markush group of dependent claim 13 to find a lack of unity of invention, examiner has also incorrectly applied the PCT provisions governing unity of invention in Markush practice. Examiner alleges that there is no unity of invention in the Markush group because the compounds identified have "no core structure therebetween" and are "not members of an art recognized class." (Office Action May 17, 2006). Unity of invention in Markush practice is governed by PCT Rule 13.2 and "special technical features" for purposes of unity of invention are shown when:

> (A1) All alternatives have a common property or activity; and
> (B1) A common structure is present, i.e., a significant structural element is shared by all of the alternatives; ***or***
> (B2) In cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

Annex B to PCT Administrative Instructions, (f)(i)(B)(2), MPEP Appendix AI, pg. AI-56.

The "alternative" heparin binding peptides claimed in claim 13 meet the (A1) requirement of a common activity - each peptide binds heparin. Moreover, applicants disagree with Examiner's finding that there is no "core structure" shared between the peptides of claim 13 in accordance with (B1). The generic formulas presented in claim 1 are directed to novel heparin binding peptides; and, the peptides of claim 13 are species of claim 1. If examiner is suggesting that there is no core structure shared between the members of the sub-set from which R_1, R_2, and R_3 are selected, no such requirement is mandated by the PCT.

Applicants also dispute examiner's finding that the alternative heparin binding peptides identified in claim 13 are not members of an art recognized class as required by (B2) above. The requirements of (B2) are further explained in the MPEP.

> In paragraph (f)(i)(B)(2), above, the words "recognized class of chemical compounds" mean that there is an expectation from the knowledge in the art that members of the class will behave in the same way in the context of the claimed invention. In other words, each member could be substituted one for the other, with the expectation that the same intended result would be achieved.

Annex B to PCT Administrative Instructions, (f)(iii), MPEP Appendix AI, pg. AI-56.

Based on the fact that the claimed heparin binding peptides build upon known consensus sequence motifs, "[t]here is an expectation from knowledge in the art that each member of the **class** [of compounds in claim 13] could be substituted one for the other, with the expectation that the same intended result would be achieved," i.e. each novel peptide defined by the claim will bind heparin.

In light of the fact that the heparin binding peptides of claim 13 share a common generic structure and belong to an art recognized class, the requirements of (A1), (B1), and (B2) identified in the PCT Administrative Instructions are met.

Requirement for a Peptide Election as the Invention

Relying upon his finding that the Markush group of claim 13 lacks unity, the examiner further maintains that applicants must elect a single species of peptide to which examination will be restricted because the heparin binding peptides "do not contain a substantial, distinguishable core structure/sequence that runs through them respectively." As previously indicated, applicants elect peptide SEQ ID NO: 5. The election is made with traverse.

First, Examiner cites no authority stating that it is permissible to refuse examination of generic claims and instead require applicants to elect a single peptide. Such an election was not required by the international searching authority. Further, in US Patent 6,855,801, claims of similar construction were completely searched, examined, and allowed without limitation to a single species.

Second, even if there is no common structure shared among the heparin binding peptides of claim 13, which is not admitted, Examiner cannot refuse to examine generic claims for members of an art recognized class when unity of invention is properly established. As discussed above, unity of invention in a Markush group can be premised on either (i) the combination of a common property or activity, and a common structure, ***or***, as the combination of a common property or activity, and membership of the alternative in a

recognized class of chemical compounds in the art to which the invention pertains. Annex B to PCT Administrative Instructions, (f)(i)(B)(2), MPEP Appendix A1, pg. AI-56.

As the PCT explicitly recognizes that unity of invention can be present when there is no common structure among group members, it is improper to restrict applicants to one peptide because of an alleged lack of structural similarity. The PCT anticipates situations where structure **cannot** be the linking quality for unity of invention purposes and provides that so long as the compounds are members of an art recognized class, examination should proceed. As indicated earlier, the heparin binding peptides of claim 13 are members of an art recognized class.

Even where species are deemed to lack unity because they are not so linked to form a single inventive concept under PCT Rule 13.1, which is not the case here, an applicant is still entitled to consideration of claims to additional species, upon allowance of a generic claim. See MPEP 1893.03(d), Rev. 3, August 2005, pg. 1800-201. There is no authority for forcing an election of species requirement, and treating the election as an "election of a single invention". Once a species is elected, examiner is still required to examine the generic invention.

Reconsideration and withdrawal of the "election of a single invention" requirement is respectfully requested.

Species Election in Groups IV and VIII

Although applicants do not elect either Group IV or Group VIII, applicants reserve the right to traverse any future species election requirements should they be made.

Conclusion

As there is unity of invention throughout the application, applicants respectfully request that conclusion to the contrary be reevaluated in light of the evidence presented.

Respectfully submitted,

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By: _____

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